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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,477	12/11/2001	Masahiro Imoto	1830/50521	4095

23911 7590 06/17/2004

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EXAMINER

RAO, DEEPAK R

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,477

Applicant(s)

IMOTO ET AL.

Examiner

Deepak R Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35, 36 and 41-58 ~~8~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35 and 41-58 ~~8~~ are rejected.
- 7) ☒ Claim(s) 36 is/~~are~~ objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

This office action is in response to the amendment filed on March 16, 2004.

Claims 35-36 and 41-58 are pending in this application.

Election/Restrictions

Applicant's elected the invention drawn to tetrahydropyrimidine compounds and the species of Compound No. 2 (page 29, Table 1). The species represents a compound of formula (I) wherein A¹ and R⁷-R¹² are hydrogen and A² is 6-chloro-pyrid-3-yl. The elected species was not found in the prior art and the search was expanded (as per the guidelines of MPEP § 803.02) to the compounds of formula (I) wherein X is -CH₂-CH₂-CH₂-; A¹ is H or alkyl; and A² is pyridyl substituted with lower alkyl or halogen and art was found.

The subject matter of compounds of formula (I) other than the above indicated subgenus and the corresponding species in claim 36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

The following rejections are withdrawn:

The rejections under 35 U.S.C. 112, second paragraph of the previous office action are withdrawn in view of the amendments.

The following rejections are maintained:

1. Claims 35 and 41-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Upshall, Chem. Abstract 77:70055, for the reasons provided in the previous office action which are incorporated here by reference.

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Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that unexpected results have been provided in the specification with respect to the claimed compounds which selectively activate $\alpha 4\beta 2$ nicotinic acetylcholine receptors and the reference does not disclose such activity for the reference compounds. However, the prior art need not disclose the newly discovered property in order for there to be a *prima facie* case of obviousness. In fact, similar properties may normally be presumed when compounds are very close in structure. Also note, there is no requirement that the prior art must suggest that the claimed compound will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. *In re Dillon*, 919 F.2d 688, 696, 16 U.S.P.Q.2d 1897, 1904 (Fed. Cir. 1991). If the prior art compound does in fact possess a particular benefit, even though the benefit is not recognized in the prior art, applicant's recognition of the benefit is not in itself sufficient to distinguish the claimed compounds from the prior art. The reference teaches that the compounds have pharmaceutical therapeutic activity based on the nicotinic properties, which is sufficient to one of ordinary skill to make the claimed compounds because similar properties are normally presumed when compounds are very close in structure. There is nothing on the record to show that the reference compounds do not possess the activity of the instant compounds. Applicants must prove that their compounds possess a property that the prior art compounds do not possess. The discovery of additional use not disclosed in the reference does not make otherwise obvious compounds unobvious. See *In re Best*, 195 USPQ 430 (CCPA 1977). The PTO can require an applicant to prove that the relevant prior art products do not necessarily or inherently possess characteristics of the claimed product. As there is no comparative data on record clearly establishing that the properties of the instant

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compounds are 'unexpected' when compared to those of the reference compounds, the rejection is maintained.

2. Claims 35 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gauthier et al., U.S. Patent No. 4,379,926, for the reasons provided in the previous office action which are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that unexpected results have been provided in the specification with respect to the claimed compounds which selectively activate $\alpha 4\beta 2$ nicotinic acetylcholine receptors and the reference does not disclose such activity or any nicotinic activity for the reference compounds. However, the prior art need not disclose the newly discovered property in order for there to be a *prima facie* case of obviousness. In fact, similar properties may normally be presumed when compounds are very close in structure. Also note, there is no requirement that the prior art must suggest that the claimed compound will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. *In re Dillon*, 919 F.2d 688, 696, 16 U.S.P.Q.2d 1897, 1904 (Fed. Cir. 1991). If the prior art compound does in fact possess a particular benefit, even though the benefit is not recognized in the prior art, applicant's recognition of the benefit is not in itself sufficient to distinguish the claimed compounds from the prior art. The reference teaches that the compounds have pharmaceutical therapeutic activity, which is sufficient to one of ordinary skill to make the claimed compounds because similar properties are normally presumed when compounds are very close in structure. There is nothing on the record to show that the reference compounds do not possess the activity

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of the instant compounds. Applicants must prove that their compounds possess a property that the prior art compounds do not possess. The discovery of additional use not disclosed in the reference does not make otherwise obvious compounds unobvious. See *In re Best*, 195 USPQ 430 (CCPA 1977). As there is no comparative data on record clearly establishing that the properties of the instant compounds are 'unexpected' when compared to those of the reference compounds, the rejection is maintained.

Allowable Subject Matter

Claim 36 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims **limited to the elected invention of 1,4,5,6-tetrahydropyrimidines having a pyridinyl substituent.**

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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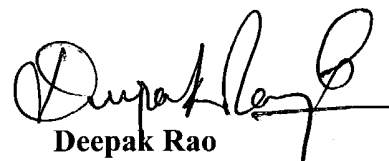
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Deepak Rao
Primary Examiner
Art Unit 1624

June 13, 2004